

**IN THE UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF MONTANA  
GREAT FALLS DIVISION**

ENVIRONMENTAL DEFENSE FUND;  
MONTANA ENVIRONMENTAL  
INFORMATION CENTER; and CITIZENS  
FOR CLEAN ENERGY,

Plaintiffs,

vs.

U.S. ENVIRONMENTAL PROTECTION  
AGENCY; and ANDREW R. WHEELER,  
in his official capacity as Administrator of  
the U.S. Environmental Protection  
Agency,

Defendants.

**4:21-cv-03-BMM**

**ORDER**

**INTRODUCTION**

Environmental Defense Fund (“EDF”), Montana Environmental Information Center (“MEIC”), and Citizens for Clean Energy (“CCE”) (collectively, “Plaintiffs”) brought this action against the U.S. Environmental Protection Agency (“EPA”) and Andrew R. Wheeler in his official capacity as Administrator of EPA (“Federal Defendants”) to challenge an EPA rulemaking. (Doc. 1). Plaintiffs allege two counts: that the final rule itself was unlawful; and that EPA’s decision to make the final rule effective on publication was unlawful. (Doc. 1 at 10–13).

Plaintiffs filed a Motion to Expedite their Motion for Partial Summary Judgment. (Doc. 7). Plaintiffs also filed concurrently a Motion for Partial Summary Judgment centered on the effective date count. (Doc. 8). Plaintiffs seek an order declaring unlawful and setting aside EPA’s decision to make the final rule effective immediately and declaring that the final rule should remain ineffective until 30 days from its publication date. (Doc. 8 at 1–2; Doc. 9 at 3–4).

Plaintiffs proposed an expedited briefing schedule for their summary judgment motion. (Doc. 7 at 3). Federal Defendants disagreed with the justification for expedited resolution, but asserted they would “nevertheless agree with the briefing schedule set forth” in Plaintiffs’ motion. (Doc. 16 at 1). The Court granted the Motion to Expedite. (Doc. 18). The Motion for Partial Summary Judgment proves fully briefed and ripe. (Docs. 8, 9, 24, 27).

## **BACKGROUND**

### *Factual Background*

President Richard Nixon established EPA in 1970 “to make a coordinated attack on the pollutants which debase the air we breathe, the water we drink, and the land that grows our food.” Reorganization Plan No. 3 of 1970 (July 9, 1970). William D. Ruckelshaus, the first EPA Administrator, further elaborated that EPA has a “broad responsibility for research, standard-setting, monitoring and enforcement with regard to five environmental hazards: air and water pollution,

solid waste disposal, radiation, and pesticides.” EPA’s First Administrator on Establishment of EPA, Press Release (Dec. 16, 1970).

EPA’s mission remains “to protect human health and the environment.” EPA achieves that mission through the implementation of these core environmental laws: the Clean Air Act (“CAA”), 42 U.S.C. §§ 7401–7671q; the Clean Water Act (“CWA”), 33 U.S.C. §§ 1251–1387; the Safe Drinking Water Act (“SDWA”), 42 U.S.C. §§ 300f–300j-26; the Toxic Substances Control Act (“TSCA”), 15 U.S.C. §§ 2601–2697; the Emergency Planning and Community Right-to-Know Act (“EPCRA”), 42 U.S.C. §§ 11001–11050; and the Federal Insecticide, Fungicide, and Rodenticide Act (“FIFRA”), 7 U.S.C. §§ 136–136y, among others.

EPA implements these substantive environmental statutes by establishing quantitative limits and standards to protect public health and the environment. Congress directed EPA through those statutes to use the “latest,” “generally accepted,” and “best available” science to inform the agency’s decisions. For one example, the CAA requires EPA to establish science-based standards to control air pollution to protect public health and welfare. *See* 42 U.S.C. § 7401(b)(1); *Am. Lung Ass’n v. Envtl. Prot. Agency*, No. 19-1140, 2021 WL 162579, at \*25–\*26 (D.C. Cir. Jan. 19, 2021) (describing the purpose and history of the CAA).

EPA sets air pollution standards known as air quality criteria that must “accurately reflect the latest scientific knowledge.” 42 U.S.C. § 7408(a)(2). EPA

must consider “all identifiable effects [of air pollutants] on public health and welfare” and “include information” on certain science-based factors “to the extent practicable” when it establishes air quality criteria. *Id.* EPA must then use these criteria to adopt National Ambient Air Quality Standards (“NAAQS”) at levels requisite to protect public health with an adequate margin of safety. *See id.* § 7409(b). The CAA further requires EPA to evaluate health risks and effects of hazardous air pollutants (“HAPs”) and to set emission standards to reduce such risks using science-based considerations. *See id.* § 7412. As part of the residual risk requirements, EPA also must investigate and report on “the actual health effects with respect to persons living in the vicinity of sources,” and “any available epidemiological or other health studies” regarding the effects of HAPs. *Id.* § 7412(f)(1)(C).

EPA relies on a wide range of scientific research to implement its standards and rules. Such research includes epidemiological studies that use dose-response data to link exposure to a pollutant, contaminant, or substance to a public health or environmental harm. Some of these epidemiological studies—particularly studies that examine small populations or populations with unique health challenges—use data that includes confidential medical or other personally identifiable information. Such information could be used to identify study participants. Federal law generally prohibits public disclosure of these data to protect the privacy of those

who participated in those studies. *See, e.g.*, Health Insurance Portability and Accountability Act (“HIPAA”) Privacy Rules, 45 C.F.R. Parts 160 and 164, Subparts A & E (establishing safeguards to protect the privacy of personal health information, and setting limits and conditions on the uses and disclosures that may be made of such information without patient authorization); 21st Century Cures Act, 42 U.S.C. § 241 (requiring government agencies to provide a certificate of confidentiality to protect the privacy of individuals participating in certain research); Privacy Act of 1974, 5 U.S.C. § 552a (precluding disclosure of personally identifiable information or records by government agencies except in very limited enumerated circumstances).

As a result, public health researchers frequently make confidential the data that underlies their findings. The scientific community has developed methodologies, such as peer review, to validate the result of studies even when the underlying data remains unavailable publicly. *See Jeremy Berg, Philip Campbell, Veronique Kiermer, Natasha Raikhel & Deborah Sweet, Joint Statement on EPA Proposed Rule and Public Availability of Data*, Nature (Apr. 30, 2018). EPA long has relied on these proven review mechanisms to ensure that the public health studies that underly regulatory decisions prove scientifically valid. The D.C. Circuit previously upheld a challenge to EPA’s practice of relying on studies with confidential underlying data. *See Am. Trucking Ass’ns, Inc. v. EPA*, 283 F.3d 355,

372 (D.C. Cir. 2002). The D.C. Circuit concluded, in part, that “requiring agencies to obtain and publicize the data underlying all studies on which they rely” would be “impractical and unnecessary.” *Id.*

#### *EPA Rulemaking*

On April 30, 2018, EPA proposed a rule to “enhanc[e] the transparency and validity of the scientific information relied upon by EPA” in its regulatory decision-making. Strengthening Transparency in Regulatory Science, 83 Fed. Reg. 18,768, 18,768–69 (Apr. 30, 2018) (“First Proposed Rule”). The First Proposed Rule would require EPA to ensure that dose response data and models underlying “pivotal regulatory science” were publicly available for validation and analysis. *See id.* at 18,770. EPA defined “pivotal regulatory science” as “studies, models, and analyses that drive the magnitude of the benefit-cost calculation, the level of a standard, or point of departure from which a reference value is calculated.” *Id.*

EPA sought to “change agency culture and practices regarding data access” by “exercis[ing] its discretionary authority to establish a policy that would preclude it from using [non-public] data in future regulatory actions.” *Id.* at 18,769 n.3. To that end, EPA’s First Proposed Rule would preclude the use of scientific studies when making regulatory decisions on the basis that the underlying data were not publicly available. The First Proposed Rule included a provision that would permit

the EPA Administrator to “exempt significant regulatory decisions” from the rule, but it failed to provide a standard to apply that exemption. *Id.* at 18,772.

EPA proposed to promulgate the First Proposed Rule “under the authority of the statutes it administers.” *Id.* at 18,768 (citing CAA, 42 U.S.C. §§ 7403, 7601(a); CWA, 33 U.S.C. §§ 1254, 1361; SDWA, 42 U.S.C. §§ 300j-1, 300j-9(a)(1); Resource Conservation and Recovery Act (“RCRA”), 42 U.S.C. §§ 6912(a)(1), 6979; Comprehensive Environmental Response, Compensation, and Liability Act (“CERCLA”), 42 U.S.C. §§ 9616, 9660; EPCRA, 42 U.S.C. § 11048; FIFRA, 7 U.S.C. §§ 136r(a), 136w; and TSCA, 15 U.S.C. § 2609).

EPA extended the comment period for the First Proposed Rule on May 25, 2018. *See* 83 Fed. Reg. 24,255, 24,256 (May 25, 2018). EPA also expanded its claim of authority to promulgate the First Proposed Rule to include the Federal Housekeeping Statute “in addition to the authorities” previously listed. *Id.* The Federal Housekeeping Statute provides “[t]he head of an Executive department or military department” with authority to “prescribe regulations for the government of his [or her] department, the conduct of its employees, the distribution and performance of its business, and the custody, use, and preservation of its records, papers, and property.” 5 U.S.C. § 301; *see also Chrysler Corp. v. Brown*, 441 U.S. 281, 310 (1979) (describing the statute as “simply a grant of authority to the agency to regulate its own affairs”).

On March 18, 2020, EPA issued a Supplemental Notice of Proposed Rulemaking “to clarify, modify and supplement certain provisions” in the First Proposed Rule. 85 Fed. Reg. 15,396, 15,398 (Mar. 18, 2020) (“Second Proposed Rule”). The Second Proposed Rule expanded the initial proposal in two ways. The Second Proposed Rule would apply to all “data and models, not only dose-response data and dose-response models.” *Id.* at 15,398. EPA also sought to apply the rule’s constraints to “influential scientific information,” rather than only to “significant regulatory decisions.” *Id.* The Second Proposed Rule still provided an avenue for the EPA Administrator to grant exemptions from the rule when compliance would be “impracticable,” but failed to provide further guidance regarding what would qualify as impracticable. *Id.* at 15,406.

EPA narrowed the statutory justification for the Second Proposed Rule. EPA no longer “propose[d] to interpret provisions of a particular statute or statutes that it administers.” *Id.* at 15,398. EPA suggested instead that it retained authority to promulgate the rule from the Federal Housekeeping Statute. *Id.*

The First Proposed Rule and the Second Proposed Rule together drew significant criticism from inside and outside the federal government. The two rules together received nearly one million public comments. Leading scientists at the National Academies of Sciences, Engineering, and Medicine cautioned that the First Proposed Rule “pose[d] a threat to the credibility of regulatory science.”

Letter from Marcia McNutt, President, Nat'l Acad. of Sciences, C.D. Mote, Jr., President, Nat'l Acad. of Eng. & Victor J. Dzau, President, Nat'l Acad. of Med., to Andrew Wheeler, Acting Administrator, EPA (July 16, 2018). EPA's own Science Advisory Board ("SAB") submitted comments critical of the Second Proposed Rule. SAB asserted that "[t]here is minimal justification provided in the Proposed Rule for why existing procedures and norms utilized across the U.S. scientific community, including the federal government, are inadequate." Science Advisory Board Consideration of the Scientific and Technical Basis of EPA's Proposed Rule Titled "Strengthening Transparency in Regulatory Science" at 17 (Apr. 24, 2020). SAB concluded that "[s]uch a proposal is inconsistent with the scientific method that requires all credible data be used to understand an issue and to allow systematic review to evaluate past research." *Id.* at 9.

On January 6, 2021, nearly two and a half years after EPA published the First Proposed Rule, EPA published its final rule in the Federal Register. Strengthening Transparency in Pivotal Science Underlying Significant Regulatory Actions and Influential Scientific Information, 86 Fed. Reg. 469 (Jan. 6, 2021) ("Final Rule"). The Final Rule provides that "when promulgating significant regulatory actions or developing influential scientific information, [EPA] will determine which studies constitute pivotal science and give greater consideration to those studies determined to be pivotal science for which the underlying dose-

response data are available in a manner sufficient for independent validation.” *Id.* at 470. EPA limited the Final Rule to apply only to dose-response data rather than all underlying data. *Id.* at 474–75. The Final Rule defines “pivotal science” as those studies “that are integral to characterizing dose-response relationships” and that “drive the requirements or quantitative analyses of EPA significant regulatory actions or influential scientific information.” *Id.* at 480.

The Final Rule provides two ways that EPA still may consider pivotal science when underlying data was not made public due to technological infeasibility or privacy. *Id.* at 477. In the first, EPA “shall” give that research “lesser consideration.” *Id.* In the second, the EPA Administrator may grant a regulation a case-by-case exemption from the Final Rule’s application. *See id.* The Final Rule limited the EPA Administrator’s discretion to grant exemptions for a limited set of reasons with a written justification. *See id.* The Final Rule further provides that when conflicts arise between it and the requirements of environmental statutes and regulations, the Final Rule limitations “will yield and the statutes and regulations will be controlling.” *Id.* at 470.

EPA did not provide guidelines or procedures for how it would implement the Final Rule. For example, EPA did not provide a process for how the agency will undertake the following activities: identify and deal with any conflicts with existing laws; designate key studies as pivotal science; document the availability of

dose-response data; and request and process an EPA Administrator exemption. *See id.* at 471 (noting plans to issue such guidance in the future).

EPA promulgated the Final Rule in reliance on authority derived from the Federal Housekeeping Statute. *Id.* EPA characterized the Final Rule as a procedural rule because it “pertains to the internal practices of the EPA.” *Id.* Although acknowledging that EPA is “not one of the ‘Executive departments’ referred to” in the Federal Housekeeping Statute, EPA argued that it gained housekeeping authority through Section 301 of the Reorganization Plan No. 3 of 1970. *Id.* (citing Reorganization Plan No. 3 of 1970, 84 Stat. 2086 (July 9, 1970)).

EPA declared the Final Rule effective upon publication in the Federal Register on January 6, 2021. *Id.* at 472. EPA provided two justifications for the Final Rule’s immediate effect. First, that the Final Rule governs internal EPA procedure, and, therefore, stands exempt from the general 30-day notice requirement of the Administrative Procedure Act (“APA”). *Id.* (citing 5 U.S.C. §§ 553(d)(2)). Second, that EPA found “good cause” to make the Final Rule effective immediately “because immediate implementation . . . is crucial for ensuring confidence in EPA decision-making.” *Id.* (citing 5 U.S.C. § 553(d)(3)).

#### *Legal Standard*

A court should grant summary judgment where the movant demonstrates that no genuine dispute exists “as to any material fact” and the movant is “entitled

to judgment as a matter of law.” Fed. R. Civ. P. 56(a). Summary judgment remains appropriate for resolving a challenge to a federal action when review will be based primarily on the administrative record. *Pit River Tribe v. U.S. Forest Serv.*, 469 F.3d 768, 778 (9th Cir. 2006). Under the APA, a reviewing court “shall . . . hold unlawful and set aside” agency action that is “arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law.” 5 U.S.C. § 706(2)(A).

## ANALYSIS

### I. Article III Standing

Plaintiffs must establish that they possess standing to invoke the Court’s jurisdiction. *See Lujan v. Defs. of Wildlife*, 504 U.S. 555, 559–60 (1992). Standing represents an “indispensable part of [a] plaintiff’s case.” *Id.* at 561. The “irreducible constitutional minimum of standing” contains three elements: injury-in-fact, causation, and redressability. *Id.* at 560; *see also Summers v. Earth Island Inst.*, 555 U.S. 488, 493 (2009). “The party invoking federal jurisdiction bears the burden of establishing these elements.” *Lujan*, 504 U.S. at 561.

Plaintiffs argue that they fulfill the standing requirement based on both organizational and representational standing theories. (Doc. 9 at 28). An organization wields organizational standing if the challenged action frustrates its goals and requires it to expend resources it would have spent in other ways. *See Comite de Jornaleros de Redondo Beach v. City of Redondo Beach*, 657 F.3d 936,

943 (9th Cir. 2011). An organization wields representational standing and may sue on behalf of its members if “(a) its members would otherwise have standing to sue in their own right; (b) the interests it seeks to protect are germane to the organization’s purpose; and (c) neither the claim asserted nor the relief requested requires the participation of individual members in the lawsuit.” *Oklevueha Native Am. Church of Haw., Inc. v. Holder*, 676 F.3d 829, 839 (9th Cir. 2012) (quoting *Hunt v. Wash. State Apple Advert. Comm’n*, 432 U.S. 333, 343 (1977)). Federal Defendants assert that Plaintiffs failed to identify a legally cognizable injury traceable to EPA’s decision to issue the Final Rule. (Doc. 24 at 13).

**a. Injury-in-Fact**

To demonstrate injury-in-fact, a plaintiff must show that it suffered “an invasion of a legally protected interest” that is “concrete and particularized” and “actual or imminent, not conjectural or hypothetical.” *Spokeo, Inc. v. Robins*, \_\_\_\_ U.S. \_\_\_, \_\_\_, 136 S. Ct. 1540, 1548 (2016) (quoting *Lujan*, 504 U.S. at 560). In a procedural standing case, a plaintiff must show that the procedures at issue are designed to protect some “threatened concrete interest” to prove an injury-in-fact. *WildEarth Guardians v. U.S. Dep’t of Agric.*, 795 F.3d 1148, 1154 (9th Cir. 2015).

**i. Procedural Injury-in-Fact**

Plaintiffs have demonstrated a procedural injury-in-fact. To establish a procedural injury-in-fact, a plaintiff “must demonstrate (1) that [it] has a

procedural right that, if exercised, could have protected [its] concrete interests, (2) that the procedures in question are designed to protect those concrete interests, and (3) that the challenged action’s threat to the plaintiff’s concrete interests is reasonably probable.” *California v. Azar*, 911 F.3d 558, 570 (9th Cir. 2018).

The APA grants Plaintiffs and their members a procedural right to petition to postpone the Final Rule’s effective date. Section 705 authorizes an agency to postpone a rule “pending judicial review” as “justice requires.” 5 U.S.C. § 705. This process provides a petitioner with immediate relief from a regulation while the courts consider the merits of a legal challenge. The Section 705 process contains a crucial caveat: a rule that is already in effect cannot be “postponed.” *Clean Air Council v. Pruitt*, 862 F.3d 1, 9 (D.C. Cir. 2017); *Nat. Res. Def. Council v. Nat’l Highway Traffic Admin.*, 894 F.3d 95, 113 (2d Cir. 2018). Plaintiffs allege that EPA unlawfully made the Final Rule effective on publication. EPA’s decision to make the Final Rule immediately effective cut off Plaintiffs’ ability to seek postponement under Section 705 as Plaintiffs would have been entitled to do under proper circumstances.

Federal Defendants respond that Plaintiffs “have not lost the opportunity to petition” EPA because other petition avenues remain available under the APA. (Doc. 24 at 16–17). Federal Defendants point to Section 553(e), which gives any “interested person the right to petition for the issuance, amendment, or repeal of a

rule.” 5 U.S.C. § 553(e). That argument ignores the distinctions, however, between the different petition remedies Congress made available through the APA. Section 705 can provide a petitioner immediate and preemptive relief from a pending regulation. *Id.* § 705. Section 705 stands available only to those petitioners who are seeking judicial redress. *Id.* Section 705 uniquely forces the agency to consider whether the ends of justice require the agency to delay the effect of a pending rule. *Id.* In comparison, Section 553(e) requires a petitioner to seek rule amendment pursuant to notice-and-comment rulemaking—a process that would take months to complete. *See Riverbend Farms, Inc. v. Madigan*, 958 F.2d 1479, 1484 (9th Cir. 1992). Petitioners would remain subject to the regulation in the interim. Plaintiffs and their members retain the unique procedural right to petition EPA to postpone the Final Rule’s effective date under Section 705.

It proves likely that Plaintiffs could have protected their concrete interests if they had been able to use the Section 705 process. “Elections have policy consequences.” *Organized Village of Kake v. U.S. Dep’t of Agric.*, 795 F.3d 956, 968 (9th Cir. 2015) (en banc); *see also Motor Vehicle Mfrs. Ass’n of U.S., Inc. v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 59 (1983) (Rehnquist, J., concurring) (“A change in administration brought about by the people casting their votes is a perfectly reasonable basis for an executive agency’s reappraisal of the costs and benefits of its programs and regulations.”). The new administration has identified

the Final Rule as a priority for immediate review. *See Protecting Public Health and the Environment and Restoring Science to Tackle the Climate Crisis, Executive Order 13,990, Sec. 2(a)(iv)* (Jan. 20, 2021). At least “some possibility” exists that Plaintiffs could have vindicated their concrete interests through a petition submitted under Section 705. *Massachusetts v. EPA*, 549 U.S. 497, 518 (2007) (requiring “some possibility” that an agency would consider a petition).

Section 705 was designed to protect Plaintiffs’ concrete interests. The Section 705 procedure to delay the implementation of a pending rule directly implicates the APA’s standard 30-day notice requirement for a substantive rule. The “primary purpose” of the 30-day notice requirement serves “to permit petitions for reconsideration and to afford persons affected a reasonable time to prepare for the effective date of a rule or rules or to take other action which the issuance may prompt.” *Nance v. EPA*, 645 F.2d 701, 708–09 (9th Cir. 1981). Such actions include a petition for the agency to delayed implementation under Section 705.

A delay provides immediate, if temporary, relief from a pending rule while a petitioner seeks judicial redress. The APA allows an agency to postpone a rule “pending judicial review” as “justice requires.” 5 U.S.C. § 705. Plaintiffs filed the above-captioned challenge to the Final Rule. Plaintiffs stand in the position contemplated by Section 705 and could have petitioned EPA to consider postponement after the agency engages in an “impartial look at the balance struck

between the two sides of the scale, as the iconic statue of the blindfolded goddess of justice holding the scales aloft depicts.” *State v. United States Bureau of Land Mgmt.*, 277 F. Supp. 3d 1106, 1122 (N.D. Cal. 2017).

The Final Rule and its immediate effect present a reasonably probable threat to Plaintiffs’ concrete financial and professional interests as organizations and through their members. For example, Plaintiffs argue that the Final Rule will harm member-scientists’ financial interests because it forces those member-scientists to adapt and restructure current applications for grant funding from the National Institutes of Health (“NIH”). (Doc. 9 at 32–36; Doc. 27 at 15–17) (citing Sarnat Decl. ¶¶ 7, 9–13; J. Lewis Decl. ¶¶ 3, 21, 23, 25–26; Balmes Decl. ¶¶ 15–19). Plaintiffs identify specific scientists and specific grants, including grants with deadlines in February 2021. (Doc. 9 at 32–36; Doc. 27 at 15–17). Plaintiffs further argue that the Final Rule threatens those same scientists’ professional interests in pursuing their intended research agendas, working with underserved communities, and informing policymaking by publishing research that will be accorded full weight. (Doc. 9 at 36–38; Doc. 27 at 15–17).

Federal Defendants respond that any alleged threat to Plaintiffs’ concrete interests rely on “speculative assumptions,” represent “self-inflicted harms,” and are “purely voluntary” in nature. (Doc. 24 at 18, 20–21). Plaintiffs’ concerns need not be certain to claim standing. They must be *reasonably probable*. *California v.*

*Azar*, 911 F.3d at 570. Plaintiffs meet that burden. Plaintiffs identified specific member-scientists who rely on dose-response data that cannot be made available for independent verification. (Doc. 27 at 16) (citing Sarnat Decl. ¶¶ 7, 9–11; J. Lewis Decl. ¶¶ 21, 23, 25; Balmes Decl. ¶ 16.). Plaintiffs’ member-scientists raised reasonable concerns that the NIH will afford their grant proposals less weight due to the potential limited application of their research on regulatory design. *See id.* A former NIH official corroborated those concerns in a declaration. *See id.* (citing Birnbaum Decl. ¶ 13) (noting in her experience that research that is “unlikely or unable to be used to inform EPA decisionmaking” or will receive “limited weight in that decisionmaking” is “unlikely” to be funded). It seems “reasonably probable” that the Final Rule threatens Plaintiffs’ identified concrete and non-speculative interests. *California v. Azar*, 911 F.3d at 570.

## **ii. Substantive Injury-in-Fact**

Plaintiffs have also demonstrated a substantive injury-in-fact. To establish a substantive injury-in-fact, a plaintiff must show that they suffered “an invasion of a legally protected interest” that is “concrete and particularized” and “actual or imminent, not conjectural or hypothetical.” *Spokeo*, \_\_\_\_ U.S. at \_\_\_, 136 S. Ct. at 1548 (quoting *Lujan*, 504 U.S. at 560). As described *supra*, Plaintiffs adequately have alleged that their member-scientists will face immediate financial expenses to conform their research agendas with the Final Rule. (Doc. 9 at 32–36; Doc. 27 at

15–17) (citing Sarnat Decl. ¶¶ 7, 9–13; J. Lewis Decl. ¶¶ 3, 21, 23, 25–26; Balmes Decl. ¶¶ 15–19). Expenses include those required to review and revise grant application materials, redesign studies, and adjust rounds of cohort recruitment to identify new study participants or provide new disclosures to existing study participants. (Doc. 9 at 32–36; Doc. 27 at 15–20) (citing Sarnat Decl. ¶¶ 7, 9–13; J. Lewis Decl. ¶¶ 3, 21, 23, 25–26; Balmes Decl. ¶¶ 15–19). Such expenses represent actual and immediate consequences for those member-scientists who are facing an impending deadline or who are actively conducting research.

#### **b. Causal Connection and Redressability**

To establish a causal connection, a plaintiff must establish a “more than attenuated” line of causation between the challenged action and the alleged harm. *Maya v. Centex Corp.*, 658 F.3d 1060, 1070 (9th Cir. 2011). Once a plaintiff has established a procedural injury-in-fact, it must demonstrate “only that [it has] a procedural right that, if exercised, could protect [its] concrete interests.” *W. Watersheds Project*, 632 F.3d at 485. A plaintiff does not have to provide “proof that an officer would have acted differently in the ‘counterfactual world’ where he was properly authorized.” *Collins v. Mnuchin*, 938 F.3d 553, 586 (5th Cir. 2019), *cert. granted*, \_\_\_ S. Ct. \_\_\_ (U.S. July 9, 2020) (No. 19-563).

Plaintiffs meet the requirements of causality and redressability. EPA’s decision to make the Final Rule effective immediately directly is traceable to

Plaintiffs' loss of their procedural right to petition for delayed implementation under the APA. A rule that is already in effect cannot be "postponed." *Clean Air Council*, 862 F.3d at 9; *Nat. Res. Def. Council*, 894 F.3d at 113. EPA's decision to make the Final Rule effective immediately cut off Plaintiffs' procedural right under Section 705. The Final Rule's immediate effect causes immediate harm to Plaintiffs and their member-scientists who must review and revise grant application materials, redesign studies, and adjust rounds of cohort recruitment to identify new study participants or provide new disclosures to existing study participants. (Doc. 9 at 32–36; Doc. 27 at 15–20) (citing Sarnat Decl. ¶¶ 7, 9–13; J. Lewis Decl. ¶¶ 3, 21, 23, 25–26; Balmes Decl. ¶¶ 15–19).

The Court remains convinced that it can redress failure to follow proper procedure through a combination of equitable and legal remedies available to correct statutory violations. The Court can remedy the deprivation of a procedural right simply by enforcing the APA's 30-day notice requirement. There is at least "some possibility" exists that the new administration would consider Plaintiffs' petition and protect Plaintiffs' concrete interests. *See Massachusetts*, 549 U.S. at 518. It is "likely, as opposed to merely speculative" that the relief sought would resolve Plaintiffs' injury-in-fact. *Lujan* 504 U.S. at 561 (internal quotation marks omitted).

Plaintiffs have satisfied the injury-in-fact, causation, and redressability requirements of standing. *See Friends of the Earth, Inc. v. Laidlaw Envtl. Servs. (TOC), Inc.*, 528 U.S. 167, 180–81 (2000).

## **II. EPA’s Rulemaking**

The APA generally requires a 30-day delay after publication of a final substantive rule before the rule can become effective. *See 5 U.S.C. § 553(d)*. The 30-day notice requirement protects “principles of fundamental fairness which require that all affected persons be afforded a reasonable time to prepare for the effective date” of a new rule “or to take other action which the issuance may prompt.” *United States v. Gavrilovic*, 551 F.2d 1099, 1104–05 (8th Cir. 1977). Congress established limited exceptions to the 30-day notice requirement. Rules of “agency organization, procedure, or practice” are explicitly exempt from the requirement. *5 U.S.C. § 553(b)(3)(A)*. An agency also may exempt a rule from the requirement with a show of “good cause.” *Id. § 553(d)(3)*.

EPA provided two justifications for its decision to make the Final Rule immediately effective on publication. EPA first asserted that the Final Rule is a procedural rule, and, therefore, stands exempt from the 30-day notice requirement. Final Rule, 86 Fed. Reg. at 472 (citing *5 U.S.C. § 553(d)(2)*). EPA next found that even if the delayed-effective date requirements applied to the Final Rule, there would be “good cause” to make the Final Rule immediately effective “because

immediate implementation of the rule . . . is crucial for ensuring confidence in EPA decision-making.” *Id.* (citing 5 U.S.C. § 553(d)(3)). The Court addresses each justification in turn.

**a. The Final Rule is a Substantive Rule**

“[T]he central distinction among agency regulations found in the APA is that between ‘substantive rules’ on the one hand and ‘interpretive rules, general statements of policy, or rules of agency organization, procedure, or practice on the other.’” *Chrysler*, 441 U.S. at 301 (quoting 5 U.S.C. §§ 553(b), (d)). A substantive rule holds “binding” effect and retains the “force of law.” *See id.* at 302; *see also Bullock v. Internal Revenue Serv.*, 401 F. Supp. 3d 1144, 1155–57 (D. Mont. 2019). A procedural rule governs internal agency proceedings, and “extends to ‘technical regulation of the form of agency action and proceedings.’” *S. Cal. Edison Co. v. FERC*, 770 F.2d 779, 783 (9th Cir. 1985) (quoting *Pickus v. U.S. Bd of Parole*, 507 F.2d 1107, 1113 (D.C. Cir. 1974)).

A procedural rule must govern and pertain to *agency procedure*. Agency actions that go “beyond formality and substantially affect[] the rights of those over whom the agency exercises authority” are not procedural rules. *Pickus*, 507 F.2d at 1113. Past examples of procedural rules remain illustrative: an agency freeze on the processing of applications for radio broadcast stations, *see Kessler v. FCC*, 326 F.2d 673, 679-83 (D.C. Cir. 1963); an agency implementation of new processes to

accelerate applications for abandoning railroad lines, *see Commonwealth of Pennsylvania v. United States*, 361 F.Supp. 208, 220–21 (M.D. Pa. 1973), aff'd, 414 U.S. 1017 (1973); an agency process to file discrimination charges, *see Hall v. EEOC*, 456 F.Supp. 695, 702 (N.D. Cal. 1978); and an agency directive specifying that audits be performed by nonagency accountants, *see Guardian Federal Savings and Loan Ass'n v. Federal Savings and Loan Insurance Corp.*, 589 F.2d 658, 665 (D.C. Cir. 1978). These examples highlight that procedural rules provide the nuts-and-bolts procedural guidelines that allow an agency to carry out its functions. Congress exempted procedural rules from the 30-day notice requirement to “ensure that agencies retain latitude in organizing their internal operations.” *Batterton v. Marshall*, 648 F.2d 694, 708 (D.C. Cir. 1980).

The Final Rule falls outside the realm of a procedural rule because it fails to provide the agency with procedural direction. It is no mere “internal house-keeping measure[.]” *Batterton*, 648 F.2d at 702. The Final Rule instead makes a substantive determination of how the agency should weigh particular scientific information in future rulemakings. The Final Rule determines outcomes rather than process. The Final Rule’s status becomes particularly clear when one examines what it is missing—any kind of procedure. EPA itself noted in its rulemaking that it would have to issue future guidance on how the rule operates procedurally. *See* Final Rule, 86 Fed. Reg. at 471. Such procedures include how EPA would designate key

studies as pivotal science, document the availability of dose-response data, identify conflicts with statutes, and provide a process for the EPA Administrator to consider exemptions. *See id.*

In comparison, the Final Rule easily meets the core requirements for a substantive rule. The “critical factor” a court must use to determine whether an agency has promulgated a substantive rule remains “the extent to which the challenged [rule] leaves the agency . . . free to exercise discretion to follow, or not to follow, the [rule] in an individual case.” *Colwell v. Dep’t of Health & Hum. Servs.*, 558 F.3d 1112, 1124 (9th Cir. 2009) (quoting *Mada-Luna v. Fitzpatrick*, 813 F.2d 1006, 1013 (9th Cir. 1987)). A rule that “merely provides guidance to agency officials in exercising their discretionary power while preserving their flexibility and their opportunity to make individualized determination[s]” is procedural. *Id.* But when a rule “narrowly limits administrative discretion or establishes a binding norm,” it “effectively replaces agency discretion with a new binding rule of substantial law.” *Id.* *See also CropLife Am. v. EPA*, 329 F.3d 876, 883 (D.C. Cir. 2003).

EPA’s Final Rule represents a substantive rule because it narrowly limits the agency’s discretion to consider certain scientific research when conducting future rulemakings. EPA bound itself absolutely when it determined that the agency “shall give greater consideration to pivotal science where the underlying dose-

response data” are “available in a manner sufficient for independent validation.” Final Rule, 86 Fed. Reg. at 492. EPA further bound itself to provide “lesser consideration” to studies where the underlying dose-response data was not made publicly available—but *only* where data was not made public due to technological infeasibility or privacy. *Id.* EPA otherwise *cannot* consider studies where underlying dose-response data was not publicly available unless the EPA Administrator grants an exemption. *See id.* EPA took the additional step of limiting EPA Administrator discretion to make such decisions. The EPA Administrator only can grant exemptions on a case-by-case basis, for one of five enumerated reasons, with a written explanation on the record. *Id.* at 493. With these substantive limitations to discretion, it appears unsurprising that EPA did not consider its own rule a procedural rule when it introduced the First Proposed Rule. *See First Proposed Rule*, 83 Fed. Reg. at 18,772.

Federal Defendants argue that the Final Rule provides discretion because it “simply provides instruction to EPA employees on the relative weight it should afford certain studies in certain rulemakings.” (Doc. 24 at 26). The Final Rule employs, however, clear language of requirement. The Final Rule provides that the EPA “*shall*” afford particular weight to particular scientific research. Final Rule, 86 Fed. Reg. at 492 (emphasis added). “Unlike the word ‘may,’ which implies discretion, the word ‘shall’ usually connotes a requirement.” *Kingdomware Techs.*,

*Inc. v. United States*, \_\_ U.S. \_\_, \_\_, 136 S. Ct. 1969, 1977 (2016). And where a rule, as here, is “couched in mandatory language, . . . a binding intent is strongly evidenced.” *Gen. Elec. Co. v. EPA*, 290 F.3d 377, 383 (D.C. Cir. 2002).

Two cases provide further support that the Final Rule represents a substantive rule. In *CropLife Am. v. EPA*, the EPA issued a press release to announce that it would no longer consider third-party human studies submitted for consideration in rulemaking. *See CropLife Am. v. EPA*, 329 F.3d 876, 881 (D.C. Cir. 2003). The D.C. Circuit concluded that such an announcement restricted EPA’s discretion in “clear and unequivocal language” that reflected “an obvious change in established agency practice.” *Id.* at 881. The same proves true in this case. EPA sought to bind itself in future regulatory decisions through clear language published in the Federal Register. EPA signaled a shift in agency practice. The agency seeks to give less weight to studies it once considered fully.

In *Batterton v. Marshall*, the U.S. Department of Labor sought to change its methods for determining unemployment rates. *Batterton*, 648 F.2d at 706. The D.C. Circuit reasoned that the Department’s rule was substantive because it “conclusively determine[d] the unemployment statistics” on which the agency could rely when it set unemployment rates. *Id.* The D.C. Circuit further elaborated that the Department’s methodology left “no room for further exercise of

administrative discretion” and that it was a “critical factor in an otherwise inflexible statutory formula for allocating monies.” *Id.* at 705–06.

Again, the same proves true in this case. EPA conclusively determined how it will weigh certain scientific studies based on the availability of underlying clinical data. EPA’s determination provides no room for discretion, and it is a critical factor in an otherwise inflexible statutory formula for setting health-based pollutant standards in statutes like the CAA. The Final Rule presents a substantive rule because it limits agency discretion. Before the rule, EPA possessed discretion to give equal—or unequal—weight to scientific research in developing new regulations, regardless of whether a study’s underlying clinical data was available. EPA now lacks that discretion.

**b. EPA Lacked “Good Cause” to Exempt the Final Rule from the 30-day Notice Requirement**

Congress provided other limited exceptions to the 30-day notice requirement, including “for good cause found and published with the rule.” 5 U.S.C. § 553(d). Notice exceptions must be “narrowly construed and only reluctantly countenanced.” *Alcaraz v. Block*, 746 F.2d 593, 612 (9th Cir. 1984). Courts have limited “good cause” for setting aside notice to “emergency situations,” and “examine closely proffered rationales justifying the elimination of public procedures.” *Am. Fed’n of Gov’t Emps., AFL-CIO v. Block*, 655 F.2d 1153, 1157 n.6 (D.C. Cir. 1981); *see also E. Bay Sanctuary Covenant v. Trump*, 932 F.3d

742, 777 (9th Cir. 2018) (“Because the good cause exception is essentially an emergency procedure . . . it is narrowly construed and only reluctantly countenanced.”).

“Congress intended to impose upon an administrative agency the burden of showing a public necessity for an early effective date,” and an agency therefore “cannot arbitrarily find good cause.” *Nw. Airlines, Inc. v. Goldschmidt*, 645 F.2d 1309, 1320 n.16 (8th Cir. 1981). Courts generally require a showing that “delay would do real harm to life, property, or public safety.” *E. Bay Sanctuary Covenant*, 932 F.3d at 777. EPA asserted in the Final Rule that it found good cause to exempt the rule from the 30-day notice requirement because the rule’s “goals of ensuring transparency and consistency” are “crucial for ensuring confidence in EPA decision-making.” Final Rule, 86 Fed. Reg. at 472. Federal Defendants provide no argument on this justification. (Doc. 24).

EPA’s limited good cause justification falls short. EPA failed to demonstrate how delayed implementation would cause real harm to life, property, or public safety. EPA failed to describe the crisis of “confidence” it sought to address. EPA failed to show a need for urgent implementation when it took more than two-and-one-half years to finalize this regulation. *See Valverde*, 628 F.3d at 1166 (holding an agency failed to show good cause when it “let seven months go by” before promulgating a rule). “Good cause cannot arise as a result of the agency’s own

delay.” *Nat. Res. Def. Council*, 894 F.3d at 114–15; *see also W. Oil & Gas Ass’n v. U.S. EPA*, 633 F.2d 803, 812 & n.12 (9th Cir. 1980). “[O]therwise, an agency unwilling to provide notice … could simply wait” until the last minute to “raise up the ‘good cause’ banner and promulgate rules without following APA procedures.” *Nat. Res. Def. Council*, 894 F.3d at 114–15. EPA lacked good cause to exempt the Final Rule from the APA’s 30-day notice requirement.

**c. The Court’s Final Rule Analysis Raises Other Issues**

Plaintiffs make two allegations in their Complaint. Plaintiffs first allege that EPA lacked the statutory authority to adopt procedural rules under the Federal Housekeeping Statute. (Doc. 1 at 10–11). Plaintiffs further allege that the Final Rule was a substantive rule that cannot be made effective immediately on publication. *See id.* at 12–13. Plaintiffs filed a Motion for Partial Summary Judgment on the *second allegation only*. (Doc. 8). Plaintiffs seek a declaration that EPA’s decision to make the rule effective immediately was unlawful and a declaration that the rule is ineffective until 30 days from the date of its publication in the Federal Register. (Doc. 9 at 43). The Court will declare as much, but such a declaration raises further legal questions beyond the scope of relief sought.

EPA asserted that it promulgated the Final Rule pursuant to its federal housekeeping authority derived from the Federal Housekeeping Statute. *See* Final Rule, 86 Fed. Reg. at 471 (citing 5 U.S.C. § 301). The Federal Housekeeping

Statute provides “a grant of authority to the agency to regulate its own affairs.” *Chrysler*, 441 U.S. at 310. The statute authorizes procedural rules “as opposed to “substantive rules.”” *Id.* at 309–10.

The Court’s above determination that the Final Rule represented a substantive rule rather than procedural rule casts into significant doubt whether EPA retains any legal basis to promulgate the Final Rule. As Federal Defendants concede in their Response, “if the Court . . . concludes that the Final Rule is a substantive rule, then the rule would lack a legal basis because EPA promulgated the rule pursuant to its housekeeping authority, which only permits the promulgation of procedural rules.” (Doc. 24 at 31 n.4).

Plaintiffs have not sought expedited relief on their first allegation that EPA issued unlawfully the Final Rule. Plaintiffs have limited their request for expedited relief *only* to EPA’s decision to exempt the Final Rule from the APA’s 30-day notice requirement. In the interest of judicial prudence, the Court will limit its Order to that issue alone.

## **CONCLUSION**

Summary judgment proves appropriate where the movant demonstrates that no genuine dispute exists “as to any material fact” and the movant is “entitled to judgment as a matter of law.” Fed. R. Civ. P. 56(a). This case presents no material facts in dispute. Plaintiffs have met their burden and are entitled to judgment as a

matter of law based on the administrative record before the Court. The Final Rule was a substantive rule. EPA did not provide good cause to exempt the Final Rule from the APA's 30-day notice requirement. EPA's decision to make the Final Rule immediately effective on publication was "arbitrary, capricious" and "otherwise not in accordance with law." 5 U.S.C. § 706(2)(A).

## **ORDER**

Accordingly, **IT IS ORDERED** that:

- Plaintiffs' Motion for Partial Summary Judgement (Doc. 8) is **GRANTED**;
- The Court declares that EPA unlawfully made the Final Rule effective immediately on publication in the Federal Register, Strengthening Transparency in Pivotal Science Underlying Significant Regulatory Actions and Influential Scientific Information, 86 Fed. Reg. 469 (Jan. 6, 2021); and
- The Court declares, therefore, that the Final Rule is ineffective until 30 days from its January 6, 2021, date of publication in the Federal Register: February 5, 2021.

Dated the 27th day of January, 2021.



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Brian Morris, Chief District Judge  
United States District Court